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(71) Applicant: MEDTRONIC, INC. [US/US]; 7000 Central Avenue Northeast, Minneapolis, MN 55432 (US).

(72) Inventor: GROSS, Jeffrey, M.; 28374 Lanuza, Mission Vie Jo, CA 92692 (US).

(74) Agents: FORREST, Peter et al.; Medtronic, Inc., MS301, 7000 Central Avenue Northeast, Minneapolis, MN 55432 (US).

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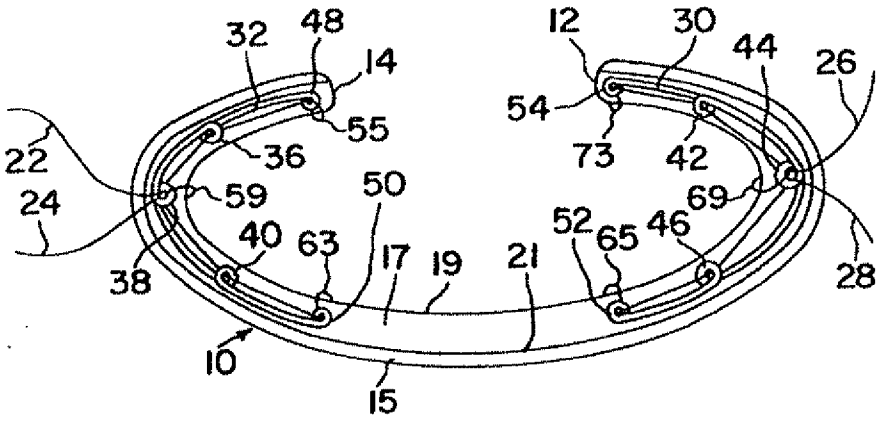

(57) Abstract

An annuloplasty ring having an adjustable configuration. The ring takes the form of a tubular sleeve surrounding frame members which may be deflected by means of drawstrings.

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ANNULOPLASTY PROSTHESIS

Background of the Invention

The present invention pertains generally to annuloplasty rings and more specifically to adjustable annuloplasty rings.

Annuloplasty prostheses, generally known as annuloplasty rings, are employed in conjunction with valvular reconstructive surgery to assist in the correction of heart valve defects such as stenosis and valvular insufficiency. Rings for use in repair of both mitral and tricuspid valves are widely known. Early annuloplasty ring designs, and most commercially available annuloplasty rings are fixed in circumference, and thus must be made available in a variety of sizes so that they may be used with valves of differing sizes. However, a number of patents propose annuloplasty rings having adjustable circumferences, including U.S. Patent No. 4,042,979, issued to Angell, U.S. Patent No. 4,290,151, issued to Massana and U.S Patent No. 5,064,431, issued to Gilbertson et al.

While some ring designs are very flexible throughout their circumference, such as the Duran annuloplasty ring, manufactured and sold by Medtronic, alternative designs employ more rigid frames which completely or partially surround the ring. Rigid or partially rigid annuloplasty rings are disclosed in U.S. Patent No. 3,656,185, U.S. Patent No. 5,061,277 and in U.S. Patent No. 5,104,407.

Summary of the Invention

The present invention provides an annuloplasty ring which may be reconfigured after installation around the valve annulus. Unlike the adjustable annuloplasty rings described above, which are adjustable only to vary the lengths of designated portions of the circumstance, the present ring may be adjusted to vary the curvature of the prosthesis, allowing for wide flexibility in adjusting the configuration of the valve annulus to assure proper valve function.

The present employs internal frame members to control the curvature of segments of the ring. The curvature of the frame members is adjustable by means of drawstrings which are employed to vary the curvature along one or more portions of

the frame members. In the preferred embodiment, two spaced, curved, frame members are employed, each employing multiple drawstrings to provide for a high degree of control of curvature. The first frame member extends from the antero-lateral trigone, partially around the posterior leaflet. No frame is provided between the antero-lateral trigone and the postero-medial trigone along the anterior portion of the mitral annulus. The second frame member extends from the postero-medial trigone partially around the posterior leaflet, but spaced from the first frame member.

No frame is provided along the posterior segment of the mitral annulus, between the ends of the first and second frame members. The annulus is thus free to move normally in the regions between the frame members, but is prevented from undergoing systolic anterior motion in the regions adjacent the frame members.

In the disclosed embodiment, the annuloplasty ring is provided with a temporary metal spacer extending between the two ends of the prosthesis, in order to simplify installation. After installation, the spacer is removed.

Brief Description of the Drawings

Figure 1 is a plan view of the invention, configured in the form of a mitral annuloplasty ring.

Figure 2 illustrates the functioning and relationship of the adjustable frame members, within the annuloplasty ring illustrated in Figure 1.

Figure 3 is a cross section through the annuloplasty ring illustrated in Figure 1.

Figures 4, 5, 6 and 7 illustrate alternative mechanisms for adjusting the curvature of the frame members illustrated in Figure 2.

Detailed Description of the Preferred Embodiments

Figure 1 illustrates a mitral annuloplasty ring according to the present invention. Externally, the ring is covered with a ribbed tubular dacron cloth sleeve 10, of moderate porosity. The ribbing of the tubular dacron sleeve 10 allows it to follow the curvature of the prosthesis without kinking of the fabric. The cross section of the tubular dacron sleeve 10 is formed into two elliptical channels by means of a longitudinal ultrasonic weld, sutures, adhesive or the like, as illustrated in Figure 3. Inner channel 17 is located adjacent the inner, concave edge of the ring and outer

channel 15 is located adjacent the outer, convex edge of the ring. Externally, a thread 11 of a different color from the surrounding dacron is used to mark the division between the inner channel 17 and the outer channel 15. Additionally, threads 13 of a different color than the surrounding dacron are placed radially in two locations to denote the ends of the internal frame members, adjacent the posterior valve annulus. Suturing to the annulus is permitted along the exterior channel 15 and along the interior channel 17 between the two radial markers 13. The sleeve is sealed at ends 12 and 14 by means of ultrasonic welds, sutures or adhesive. As implanted, the first end 12 is adapted to located adjacent the postero-medial trigone and the second end 14 is adapted to be located adjacent the antero-lateral trigone, with the prosthesis generally extending around the posterior leaflet. A spacer 16 is sutured to the ends 12 and 14 of the prosthesis by means of sutures 18 and 20. Spacer 16 aids in maintaining the prosthesis in an appropriate configuration during shipment and during implantation, and provides an appropriate frame of reference to assist in proper location of ends 12 and 14 relative to the valve annulus. The spacer may be fabricated of MP35N alloy, or other similar inert biocompatible metal and is removed after the ring is secured in place to the valve annulus. Extending from the top of each side of the inner channel 17 are drawstrings 22, 24, 26 and 28 which serve to adjust the curvature of the prosthesis, as described below.

Figure 2 illustrates the internal structure of the ring. In this view, the outline of the dacron sleeve 10 is indicated at 19, with the division between inner channel 17 and outer channel 15 indicated by line 21. Mounted within the sleeve 10 are frame members 30 and 32. The frame members 30 and 32 are manufactured of MP35N alloy or other biocompatible metal wire, and extend from the ends (12 and 14) of the prosthesis, around the prosthesis, to two points adjacent the central portion of prosthesis, which at implant will be adjacent the posterior leaflet. The ends of the frame members are spaced from one another within sleeve 10, so that the valve annulus may assume its normal configuration during opening and closing of the valves in this region intermediate frame members 30 and 32.

Each of the two frames 30 and 32 are wound to define loops 36, 38, 40, 42, 44 and 46, spaced along the length of the frame members 30 and 32.

The ends of the frame members are wound to define loops 48, 50, 52 and 54 which may serve as anchor points for location of drawstrings and may serve as loops through which drawstrings pass. Similarly, each of the loops 36, 38, 40, 42, 44 and 46 may also serve as anchoring points for drawstrings and/or as loops through which a drawstring may pass. Loops 38, 44, 48, 50, 52 and 54 are sutured to the tubular dacron sleeve, as illustrated at 59, 69, 55, 63, 65 and 73. These sutures maintain the frame members 30 and 32 at their proper locations within the inner channel 17 of tubular sleeve 10.

As illustrated, each of the two frame members is provided with a pair of drawstrings 22, 24, 26 and 28. For frame member 32, drawstrings 22 and 24 both enter through the central loop 38, and extend through intermediate loops 36 and 40 to opposite ends of the frame member where they are anchored at end loops 48 and 50, respectively. Tension applied to drawstring 22 thus causes deflection of frame member 32 between loops 38 and 48 in a way similar to the way a fishing pole bends when a fish is hooked. Similarly, tension applied to draw string 24 causes deflection of the frame member 32 between loops 38 and 50. Drawstrings 26 and 28 are routed and function in an equivalent fashion with regard to frame member 30. Drawstrings 22, 24, 26 and 28 may be prolene type sutures, preferably coated with Teflon or other low friction material.

During implantation, the ring is mounted around the mitral valve annulus in a conventional fashion, with sutures appropriately spaced and located to provide any necessary reduction in overall annulus circumference. This much of the implant procedure corresponds to the procedures used to implant prior art nonadjustable prostheses such as the Duran annuloplasty ring manufactured and sold by Medtronic or the Carpentier annuloplasty rings sold by Baxter International, Inc. Following suturing of the ring to the valve annulus, the spacer 16 is removed by trimming of sutures 18 and 20 (Fig. 1), and the curvature of the ring is adjusted by applying tension to appropriate ones of drawstrings 22, 24, 26 and 28 to assure proper annulus configuration and coaption of the valve leaflets. After the prosthesis has assumed an appropriate curvature, the drawstrings are tied at their point of exit from the annuloplasty ring, so that the desired configuration will be maintained.

Figure 3 illustrates a cross section through the ring as illustrated in Figure 1. In this view the elliptical configurations of inner channel 17 and outer channel 15 are visible. Also illustrated are threads 23, which are employed to create the division between the inner and outer channels. Frame member 30 is visible in cross section.

Figure 4 illustrates an alternative mechanism for stringing the drawstrings with respect to the frame members. Only frame member 32 is illustrated, however, it is to be understood that the same or a different stringing pattern for the drawstrings may be employed on the second frame member which would accompany frame member 32 in the prosthesis. The same is true of Figures 4-6 which also illustrate alternative relationships between frame member 30 or frame member 32 and the drawstrings.

In Figure 3, drawstrings 76 and 78 both enter the central loop 38, preceding to end loops 48 and 50, passing through loops 36 and 40, respectively, as illustrated in Figure 2. However, rather than being anchored to loops 48 and 50, the drawstrings proceed through the loops back to intermediate loops 36 and 40, where they are anchored.

Figure 5 corresponds to Figure 4 with the exception that in the case of Figure 4, drawstrings 80 and 82 are routed through intermediate loops 36 and 40 and are anchored at central loop 38. The drawstring configurations of Figure 4 and 5 provide an improved mechanical ratio as compared to the drawstring configuration in Figure 2, with the result that a greater extension of the drawstring is required to effect a predetermined curvature in the frame member 32.

Figure 6 and Figure 7 illustrate alternative drawstring configurations directed toward providing enhanced ability to deflect the frame around the central loop. In Figure 5, drawstrings 26 and 28 enter the prosthesis through intermediate loops 42 and 46, respectively, passing through central loop 44, and then extending through loops 42 and 46 to end loops 52 and 54, to which the drawstrings are anchored. Tension applied to drawstring 26 thus causes the prosthesis to flex between loops 42 and 52. Similarly, tension applied to drawstring 28 causes the frame member 30 to flex between loops 46 and 54.

Figure 7 illustrates a drawstring configuration which is a hybrid of those illustrated in Figures 2 and 6, with drawstring 26 routed corresponding to drawstring 26 in Figure 2 and drawstring 28 routed as in Figure 6.

As can be seen, a wide variety of drawstring configurations are available, with variations in drawstring configuration readily employed to determine the location and amount of flexing of the frame members induced by tension on the drawstrings. Similarly, it should be understood frame members having greater or fewer numbers of loops, of greater or lesser diameters, are also within the scope of the present invention. It is believed that as prosthesis of this general type are further developed, specific frame configurations and drawstring configurations may be developed which are particularly optimized for correction of particular types of mitral valve defects.

In the disclosed embodiment, two independent frame members are provided, spaced from one another within the inner channel of the sleeve. However, a single frame member extending around the circumference of the prosthesis, whether configured as an open or closed curve might also be substituted for some applications.

While the present invention is disclosed as a prosthesis having fixed length, the adjustable frame members of the present invention may also be incorporated in prosthesis having adjustable lengths. In such cases, it is to be expected that adjustment of the overall length of the prosthesis would be accomplished by a set of one or more drawstrings employed to lengthen or shorten the spacing between the frames. Similarly, while the disclosed embodiment takes the form of a mitral annuloplasty prosthesis, it is believed that the basic mechanism for adjustment of the curvature of the frame members may be of value in other applications, including other valve annuloplasty prostheses as well as prostheses designed to correct other deformations of annular or tubular structures within the body.

As such, the above disclosures should be taken as exemplary, rather than limiting with regard to the claims that follow.

In conjunction with the above application, I claim:

CLAIMS

1. An annuloplasty prosthesis comprising:

a first frame member;

a fabric, covering, said frame member; and

means for applying tension between two points on said frame member to cause deflection of said frame member.

2. An annuloplasty prosthesis according to claim 1 wherein said means for applying tension comprises a drawstring.

3. An annuloplasty prosthesis according to claim 2 wherein said first frame member comprises a metal wire.

4. An annuloplasty prosthesis according to claim 3 wherein said metal wire is wound to define a loop.

5. An annuloplasty prosthesis according to claim 4 wherein said drawstring is affixed to said metal wire and passes through said loop.

6. An annuloplasty prosthesis according to claim 1 further comprising a second frame member, spaced from said first frame member and located within said fabric and means for applying tension between two points on said second frame member to cause deflection of said second frame member.

7. An annuloplasty prosthesis according to claim 6 wherein said fabric comprises a tubular sleeve, divided into two internal channels and wherein said first and second frame members are located within one of said channels.

8. An annuloplasty prosthesis according to claim 1 wherein said fabric comprises a tubular sleeve, divided into two internal channels and wherein said first frame member is located within one of said channels.

9. An annuloplasty prosthesis according to claim 7 or claim 8 wherein said prosthesis follows a curve and has an inner, concave edge and an outer, convex edge, and wherein said one of said channels is adjacent said inner edge.

10. A mitral annuloplasty prosthesis comprising:

a fabric sheath;

first and second frame members mounted within said sheath and spaced from one another, said frame members configured such that after implant, said first frame member extends from the antero-lateral trigone to a first point adjacent the posterior leaflet and said second frame member extends from the postero-medial trigone to a second point adjacent the posterior leaflet, said first and second points spaced from one another.

11. A mitral annuloplasty prosthesis according to claim 10 further comprising means for applying tension between two points on said frame members to cause deflection of said frame members.

12. A mitral annuloplasty prosthesis according to claim 11 wherein said means for applying tension comprise drawstrings.

13. A mitral annuloplasty prosthesis according to claim 10 wherein said frame members comprise metal wires.

14. A mitral annuloplasty prosthesis according to claim 13 wherein said metal wires are wound to define loops.

15. A mitral annuloplasty prosthesis according to claim 14 wherein said drawstrings are affixed to said frame members and pass through said loops.

16. A mitral annuloplasty prosthesis according to claim 10 wherein said fabric comprises a tubular sleeve, divided into two internal channels and wherein said first and second frame members are located within one of said channels.

17. A mitral annuloplasty prosthesis according to claim 16 wherein said prosthesis follows a curve and has an inner, concave edge and an outer, convex edge, and wherein said one of said channels is adjacent said inner edge.

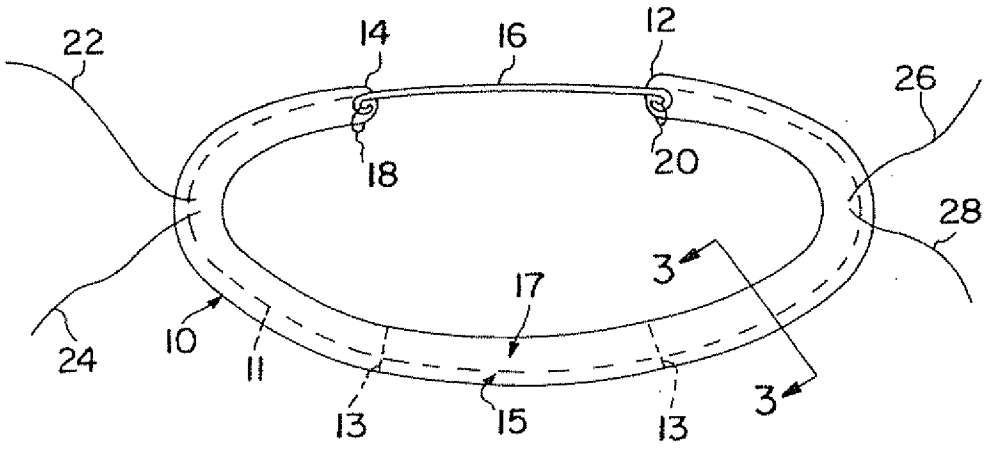
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FIG. 1

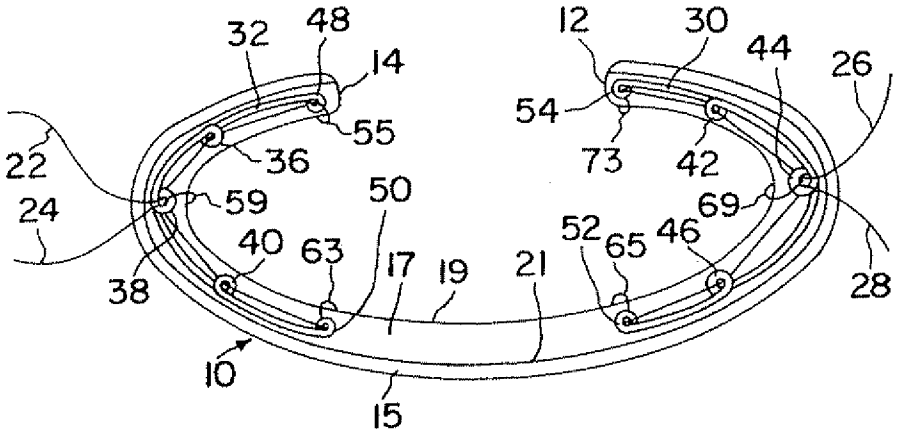
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FIG. 2

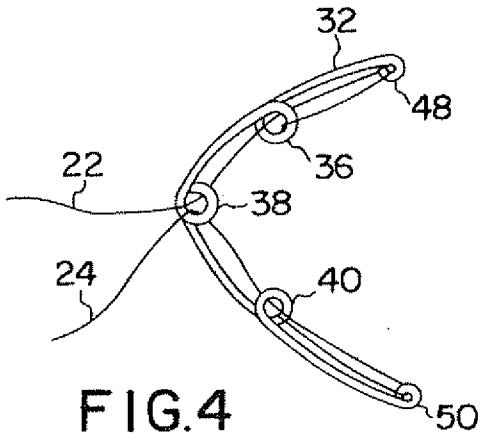

FIG.4

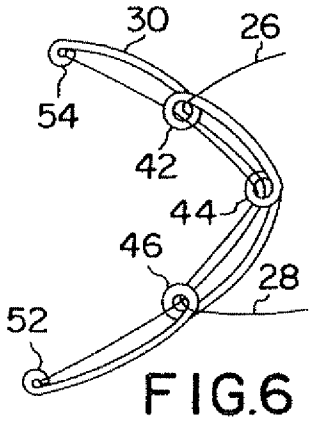

FIG.6

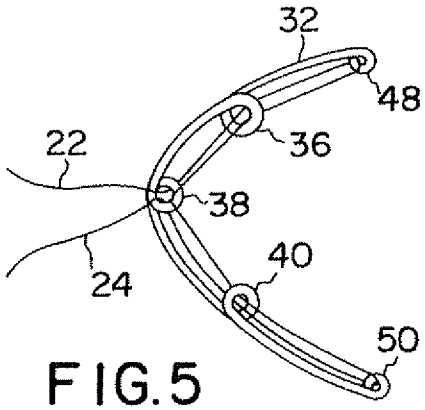

FIG.5

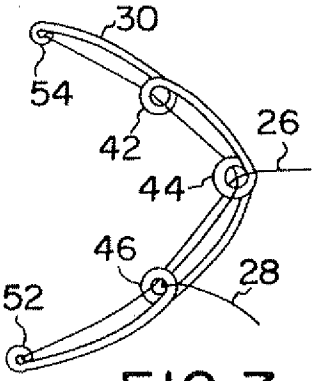

FIG. 7

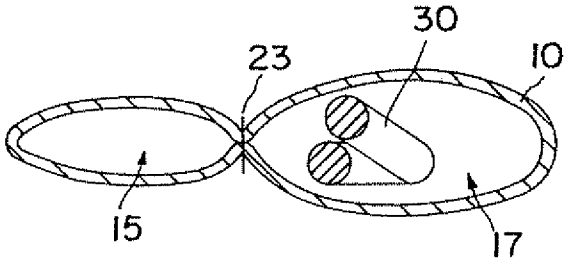

FIG. 3

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 96/18786

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 201 880 A (WRIGHT) 13 April 1993 see the whole document	1-5,8,9 6,7, 13-17
X Y	US 4 917 698 A (CARPENTIER) 17 April 1990 see column 5, line 9 - column 6, line 35; figures	10-12 6,7, 13-17
X	US 4 489 446 A (REED) 25 December 1984 see abstract; figures	10
A	DE 32 30 858 A (AHMADI) 1 March 1984	
A	US 4 042 979 A (ANGELL) 23 August 1977 cited in the application	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
17 March 1997	27. 03. 97
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Form PCT/ISA/210 (second sheet) (July 1992)

ernational application No.

INTERNATIONAL SEARCH REPORT

PCT/US 96/ 18786

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.Claims: 1- 9 An annuloplasty prostesis comprising means for applying tension
2.Claims:10-17 A mitral annuloplasty prostesis comprising first and second frame members

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/US 96/18786

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